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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SONNETT, KATHLEEN C

ART UNIT PAPER NUMBER

3731

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/521,966

Applicant(s)

FUSERI ET AL.

Examiner

Kathleen Sonnett

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12, 13, 15-17, 19 and 21 is/are rejected.
- 7) ☒ Claim(s) 2-3, 7-8, 10-11, 14, 17, 19-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/21/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. **Claims 2, 17, and 19** are objected to because of the use of “preferably” before the ranges (see also 35 USC 112 rejections for claim 17 and 19 regarding the use of a broad range followed by a narrow range in a claim). The use of “preferably” makes it unclear whether the range is actually being claimed. Appropriate correction is required.
2. **Claims 3, 7, and 8** are similarly objected to because of the use of “preferably” preceding “low” in claim 3, in lines 4, 15, and 20 of claim 7, and in line 5 of claim 8. The use of “preferably” seems to render that particular limitation optional. The examiner treated these limitations as preferable, but not necessary for prior art to read on the claim. Appropriate correction is required.
3. Claim 7 also includes a minor typographical error in line 8 of the claim: an “A” appears between “said” and “blocking zone”.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. **Claims 1, 3, 4, 5, 7, 8, 10, 12, 17, 19, and 20** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 1 recites the limitation “said bearing element” in line 14 of the claim. There is insufficient antecedent basis for this limitation in the claim.

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7. Claim 3 recites the limitation "said contact zone" in line 4 of the claim and "said two ends of the strands of thread" in line 6. There is insufficient antecedent basis for these limitations in the claim. Similarly, the following claims recite the limitation "said contact zone": claims 4 (lines 3, 5, 8, 11, 17), 5 (lines 3, 5, 7), 7 (lines 10, 12), 8 (line 6), 10 (line 4), 12 (line 6) and 20 (line 5). It has been assumed by the examiner that the contact zone and bearing surface are the same since they have the same reference number (4₁).

8. Additionally, claim 4 recites the limitation "said final adjusted distance" in line 15 of the claim, which lacks antecedent basis.

9. Additionally, in claim 7, "said first *minimum* spacer" lacks antecedent basis.

10. Additionally, claim 8 recites the limitation "said suture orifices" in line 4 of the claim, which lacks antecedent basis.

11. Additionally, claim 20 recites the limitation "said second spacer element", which lacks antecedent basis.

12. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 17 and 19 recite the broad recitation "preferably lying in the range 0.2 N to 20 N", and the claim also recites "more preferably greater than 10 N" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

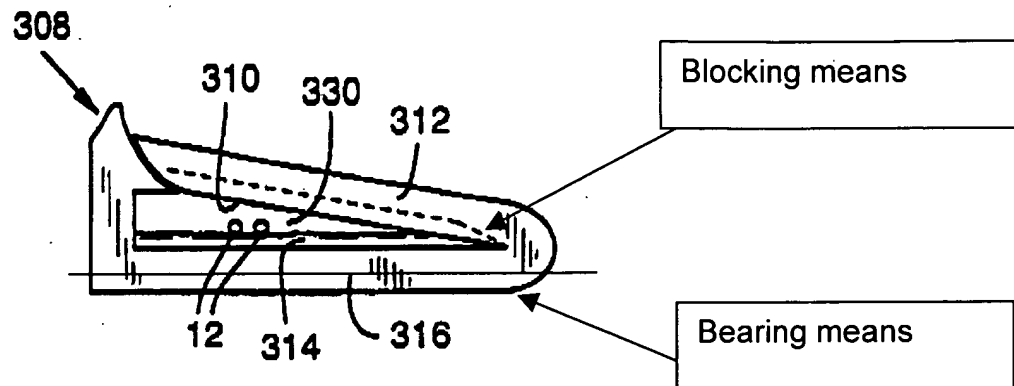
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. **Claims 1, 3, 15, and 21** are rejected under 35 U.S.C. 102(b) as being anticipated by Hayhurst (U.S. 5,474,572). Hayhurst discloses an implantable device (col. 1, lines 59-65) for semiautomatic suturing using a surgical thread, the suturing enabling biological and/or artificial tissues to be united, the device comprising blocking means (310) enabling two strands of the thread of a suture to be connected together in a blocking zone (330), and comprising a bearing element having a bearing surface (bottom surface of 316 as seen in Fig. 12) for bearing against the tissues to be sutured together, the device being characterized in that it further comprises controlled tensioning means (123, fig. 5) for applying controlled tensioning to said thread, and

suitable for exerting a tension having a first predetermined tension value after the two strands of said thread have been blocked together using said blocking means, with the junction between said bearing element and said blocking zone of the device being provided by said controlled tensioning means.

15. Regarding claim 3, Hayhurst discloses an initial distance in which two ends of suture can be blocked together with the thread being at a tension that is preferably low and a final distance for exerting a controlled tension having a first predetermined tension value. In particular, the device in its open configuration (shown in Fig. 12) holds the suture together at a tension that is low and in its closed configuration (13) holds the suture at a first predetermined tension value.

16. Regarding claim 15, Hayhurst discloses a blocking means (312) that includes two surfaces (310, 314) capable of moving between a spaced apart position in which it is possible to insert strands of thread between the two blocking surfaces and suitable for blocking the strands of thread together by friction between the threads and the blocking surfaces once the surfaces are in a close-together, blocking position, the displacement of the two surfaces between the spaced-apart position and the close-together position automatically triggering the tensioning of the threads after blocking. A user can grasp suture that is engaged with tissue at a desired tension and fasten the device onto the suture, thereby triggering the tensioning of the threads by the device.



17. Regarding claim 16, the blocking of strands of thread by the blocking means (312) is capable of being triggered automatically.
18. Regarding claim 21, see col. 3 lines 39-40.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. **Claims 2, 8, and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayhurst in view of Dakin et al. (U.S. 6,368,326). Hayhurst discloses the invention substantially as stated above and the blocking means is suitable for triggering the tensioning of the threads to a predetermined tension. However, Hayhurst does not disclose the tension value falling in the range of 0.1N to 10N or 0.2N to 20N.

21. However, Dakin et al. discloses that it is old and well known in the art to use sutures to suture together bone fragments together. Dakin et al. further discloses that the suture needs to be under a tension of about 5N or more (col. 4, lines 54-65). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Hayhurst to allow for the blocking means to achieve a tensioning of between 0.1 to 10N as made obvious by Dakin et al. in order to be able to fasten two fragments of bone together with the device.

22. Regarding claim 8, the thread can be cut between the blocking zone and suture orifices in tissue.

23. **Claims 4-7, 12, and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayhurst (5,474,572) in view of Rubricius (U.S. 3,766,925). Hayhurst discloses the invention substantially as stated above, including controlled tensioning means that adjusts the distance between the blocking zone (330) and the bearing surface (contact zone). Hayhurst discloses a first link element (hook 131) that holds the thread at an initial tension and corresponds to a distance in which the blocking zone and bearing surface (contact zone) are in close-together position by applying compression compared with a spaced-apart, rest position but fails to disclose a position of force equilibrium in which this distance is no longer controlled by the first link element, this distance corresponding to the final distance. The examiner is now regarding the initial distance as the distance between the blocking zone and bearing surface (contact zone) when the blocking zone is being held by the hook (131).

24. However, Rubricius discloses that it is old and well known to use clamping devices for medical purposes that have several teeth (8) that allow for a cam-action lever arm that provides a high mechanical force. Rubricius teaches that the cam-action lever allows the clamp to impart varying amounts of force on the object that is being clamped (col. 2 lines 41-15). Hayhurst discloses that his device is slid along suture and passed through an arthroscopic incision until it reaches the tissue where the suture is to be secured (col. 1 lines 55-65). Adding the cam-action lever aspect to the Hayhurst device would allow the device to be loosely fastened so that it is attached to the suture while it is slid down the suture and then fastened so that the suture can no longer slip within it once the device reaches the tissue. In particular, the additional link elements would allow a user to fasten the device such that it does not slid freely but can still be slid along the suture by the user so the device can be held at intermediate positions during surgery. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Hayhurst to include multiple link elements as made obvious by Rubricius in order to gain the advantage of being able to adjust how tightly fastened the suture is to the device to better control intermediate positioning during surgery.

25. Regarding claim 5, the initial distance is obtained using the first link element (hook 131) and the final distance can be implemented by releasing the first link element so that another link element of the modified device can be engaged.

26. Regarding claim 6, the first link element is suitable for cooperating with the blocking means in such a manner that the first link element is released once the strands of thread have been blocked together.

27. Regarding claim 7, the modified device of Hayhurst is *suitable* for cooperating with a placing instrument to which it is secured preferably via a top portion corresponding to the blocking zone such that prior to the bearing surface coming in contact with tissue, the resilient junction means are at rest and the bearing surface and the blocking zone are in a spaced apart position (fig. 12). When a user presses the bearing surface (contact zone) against the tissue for suturing with an instrument that, for example, holds the blocking zone (312), the resilient junction means will be put into compression and the distance between the contact zone and the blocking zone decreases to an initial distance controlled by a first link element (spacer). A final distance can be obtained by further compression on the fastener so that the next link element is engaged (cam-action).

28. Regarding claim 12, the device is U-shaped comprising a bottom first branch defining the bearing surface (316), a top second branch including a blocking zone and secured with or cooperating with the blocking means (312), and a junction element (123; fig. 5) between the first and second branches being made of a semirigid material presenting an elasticity and preferably being a curved junction element providing a hairpin junction between the first and second branches (col. 3 lines 39-50).

29. Regarding claim 13, junction element (123) is being considered a spring blade.

30. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayhurst in view of Egan et al. (U.S. 6,174,324). Hayhurst discloses the invention substantially as stated above, but fails to disclose guide means enabling the two strands of thread to be held laterally spaced apart from each other at suture orifices in the tissue.

31. However, Egan et al. disclose that it is old and well known in the art to include contours in which suture strands fit in order to maximize the contact between the fastening device and the suture (col. 4 line 52-56 and col. 5 lines 3-6). These recesses hold the sutures laterally spaced apart from each other at the suture orifices in the tissue since the fastener is pushed down into contact with the tissue. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Hayhurst to include contours in which the strands fit as made obvious by Egan et al. in order to provide guide means that ensure maximum contact between the suture and fastener device.

Allowable Subject Matter

32. **Claims 10, 11, 14, 18 and 20** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
7/26/2006


GLENN K. DAWSON
PRIMARY EXAMINER

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